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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,988	05/06/2002	Masataka Nadaoka	2002-0074A	8710

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WENDEROTH, LIND & PONACK, L.L.P.
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SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER

CHIN, CHRISTOPHER L

ART UNIT	PAPER NUMBER
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1641

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12/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/031,988

Applicant(s)

NADAOKA ET AL.

Examiner

Christopher L. Chin

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-12, 17-22, 25-31, 36-40, 42, 43, 45 and 46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-12, 17-22, 25-31, 36-40, 42, 43, 45, and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 1-3, 6-12, 17-22, 25-31, 36-40, 42, 43, 45, and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 are vague because it is not clear as to how the volume of the cavity part provides for a B/F separation of the marker reagent. The space formed by the cavity part should contain some of the sample solution and reconstituted marker reagent once a sample has been applied to the biosensor but a space alone cannot perform a B/F separation of the marker reagent. There is no means within the space to separate bound marker reagent from free marker reagent.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 10, 11, 17-22, 29, 30, 36-40, 42, 43, 45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakaya et al (EP 1 003 038 A1) in view of Wenz et al (US Patent 3,715,192) for the reasons of record.

In response to this rejection, Applicants argue that Nakaya and Wenz fail to teach a cavity part with a volume that provides for execution of B/F separation of a marker reagent.

Applicant's arguments have been considered but are not convincing. Wenz teaches the cavity part recited in the instant biosensor and motivation for adding it to the device of Nakaya was set forth in the previous office action. Since the instant claims fail to recite any limitation that distinguishes the instant cavity part from the cavity part of Wenz, it is the Examiner's position that the cavity part of Wenz can perform the function of performing a B/F separation of marker reagent.

4. Claims 6 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakaya et al in view of Wenz et al as applied to claims 1-2 above, and further in view of Bernstein et al (US 5,824,268) for the reasons of record.

In response to this rejection, Applicants argue that Bernstein fails to cure the deficiencies of Nakaya and Wenz.

Applicant's arguments have been considered but are not convincing. As pointed out above, there are no deficiencies in the rejection of Nakaya in view of Wenz for Bernstein to cure.

5. Claims 7, 12, 26, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakaya et al in view of Wenz et al as applied to claims 1-2 above, and further in view of Killeen et al (US Patent 5,166,051) for the reasons of record.

In response to this rejection, Applicants argue that Killeen fails to cure the deficiencies of Nakaya and Wenz.

Applicant's arguments have been considered but are not convincing. As pointed out above, there are no deficiencies in the rejection of Nakaya in view of Wenz for Killeen to cure.

6. Claims 8 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakaya et al in view of Wenz et al as applied to claims 1-2 above, and further in view of Barr (US Patent 4,252,538) for the reasons of record.

In response to this rejection, Applicants argue that Barr fails to cure the deficiencies of Nakaya and Wenz.

Applicant's arguments have been considered but are not convincing. As pointed out above, there are no deficiencies in the rejection of Nakaya in view of Wenz for Barr to cure.

7. Claims 9 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakaya et al in view of Wenz et al as applied to claims 1-2 above, and further in view of Allen et al (US Patent 5,416,000) for the reasons of record.

In response to this rejection, Applicants argue that Allen fails to cure the deficiencies of Nakaya and Wenz.

Applicant's arguments have been considered but are not convincing. As pointed out above, there are no deficiencies in the rejection of Nakaya in view of Wenz for Allen to cure.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-3, 6-12, 17-22, 25-31, 36-40, 42, 43, 45, and 46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 10/069,845 in view of Wenz et al (US Patent 3,715,192) for the reasons of record.

This is a provisional obviousness-type double patenting rejection.

10. The above provisional obviousness-type double patenting rejection is representative of double patenting rejections that are necessary between the instant application and a number of copending applications. The following list discloses the serial numbers of the other copending applications that would require similar provisional obviousness-type double patenting rejections as applied supra: 10/398,711 (claims 1-19) and 10/048,727 (claims 1-11)

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L. Chin whose telephone number is (571) 272-0815. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Christopher L. Chin
Primary Examiner
Art Unit 1641

12/5/07